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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,797	10/10/2003	Paul A. Spence	GUID-101CON4	2180
36154 7590 04/21/2009 LAW OFFICE OF ALAN W. CANNON 942 MESA OAK COURT SUNNYVALE, CA 94086			EXAMINER RYCKMAN, MELISSA K	
			ART UNIT 3773	PAPER NUMBER
			MAIL DATE 04/21/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/683,797	Applicant(s) SPENCE ET AL.	
	Examiner MELISSA RYCKMAN	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 11, 17, 19, 43 and 71-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2, 11, 17, 19, 43 and 71-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☐ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413) |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) ☐ Information Disclosure Statement(s) (PTO/SB/08) | 5) ☐ Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) ☐ Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/27/09 has been entered.

Claim Objections

Claims 91 and 92 should be amended to start with a capital letter and have one comma after the claim number.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2,11,17,19,71,72,74-77,79,83-85 and 87-92 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker (U.S. Patent No. 6,221,102).

Baker teaches an anastomotic apparatus (capable of being used for as an anastomotic apparatus) for placing an inside edge surface of an incision in a first vessel in healing contact with an inside edge surface of an incision in a second vessel to

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establish flow between the vessels (capable of being used as described), said apparatus comprising:

- a sinuous, stiffening framework (138) having a plurality of malleable sections (Fig. 11) formed of a deformable material which causes the framework to remain in a second configuration after being deformed from a first configuration even after cessation of application of deformation force used to deform said framework into said second configuration (the delivery balloon is the force that deforms the framework, and the hooks attach too the tissue, so when the balloon is removed the framework does not return to the first configuration, as the framework is now attached to the tissue).
- each said malleable section comprising a curved apex (133) each said apex extending further peripherally outwardly (138 extends peripherally outwardly) than a remainder of portions of said malleable section forming the remainder of said malleable section, respectively
- means for attaching (151) said stiffening framework to the vessels to hold the inside edges of the incisions in contact while permitting the framework to be shaped to define a flow path between the vessels
- means for attaching (151) are configured to orient the edge surfaces of the first and second vessels to align the edge surfaces to join the first and second vessels in side-to-side contact with each other (capable of being used in this manner)

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- means for attaching are configured to orient the edge surfaces of the first and second vessels to align the edge surfaces to join the first and second vessels in end-to-side contact with each other (capable of being used in this manner)
- a tool (64) having a head configured to be inserted into one of the vessels to attach said means for attaching to the vessel, said head located at a distal end portion of said tool, said head extending transversely to a longitudinal axis of said tool and having a bypass channel defined therethrough and extending transversely to the longitudinal axis, for maintaining blood flow through the vessel when said head is inserted into the vessel (Fig. 14)
- a hemostatic medium (hole 133 tissue in growth can occur in this location) positioned to contact the outside surfaces of the first and second vessels as the edge surfaces of the incisions are brought into contact
- said hemostatic medium comprises a cuff (portion of 151 that is flat along 138)
- said hemostatic medium comprises an oval-shaped flexible body (hole 133 is oval)
- said head comprises an anvil (Fig. 14)
- said anvil is larger than the incision in the vessel into which it is inserted, said anvil configured to be button-holed into the vessel through the incision (Fig. 14)

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- said stiffening framework comprises a single cuff (136) and said means for attaching comprise vessel attaching elements extending from said single cuff and adapted to attach to the first and second vessels (capable of performing this function)
- said stiffening framework comprises first (132) and second (136) cuffs, said first cuff configured to be attached to the first vessel and said second cuff configured to be attached to the second vessel (capable of performing this function)
- said stiffening framework is sinuous in shape and comprises a plurality of malleable sections (Fig. 11)
- said means (one of 151) for attaching comprise tissue retention pins (151)
- docking extensions (one of 151) extending from said stiffening framework, said docking extensions configured to be manipulated to deform said stiffening framework into said second configuration
- said malleable sections (one of 151) comprise arch-shaped malleable sections, the arch shape of each said malleable section comprising a curved apex, each said apex extending further peripherally outwardly than a remainder of portions of said malleable section forming the remainder of the arch shape, respectively

Claim 43 is rejected under 35 U.S.C. 102(b) as being anticipated by Schomacher (U.S. Patent No. 4,233,981).

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Schomacher teaches a method of performing an anastomosis comprising:

A) defining an incision in a first vessel;

B) defining an incision in a second vessel;

C) fastening a mounting structure (1) on the first vessel in surrounding relationship to the incision in the first vessel such that the mounting structure surrounds the incision in the first vessel;

D) fastening the mounting structure (2) to the second vessel in surrounding relationship to the incision therein, such that the mounting structure surrounds the incision in the second vessel, and to bring inside edges of the incisions in the first and second vessels into healing contact while providing an open flow path between the vessels through the incisions

E) shaping, by bending the mounting structure to define a desired flow area between the first and second vessels (when the tissue moves the device moves)

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 11,17,19,43, and 71-92 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over the claims of U.S. Patent Numbers, 5868763, 6565581,6190397. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent listed above disclose all the limitations of the current invention.

Response to Arguments

Applicant's arguments filed 1/27/09 have been fully considered but they are not persuasive. The applicant generally argues:

- Baker teaches the opposite of the current application regarding the first and second configurations
- Schomacher does not teach shaping, by bending the mounting structure to define a desired flow area between the vessels

The examiner maintains that Baker teaches the claimed invention, the applicant does not claim what the first or second configurations are. Baker teaches using a balloon to expand the device, when the balloon is removed the device remains in the expanded shape. The examiner directs the applicant to col. 4, ll. 55,56 of

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Schomacher, Schomacher teaches a soft elastic material capable of following the movement of the vessel, this is inherently shaping by bending the structure to define a desired flow area, because when the material follows the movement of the vessel there is bending in the structure, defining a desired flow area.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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MKR

/Melissa Ryckman/

Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773